

From the
 INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

see form PCT/ISA/220

WRITTEN OPINION OF THE
 INTERNATIONAL SEARCHING AUTHORITY
 (PCT Rule 43bis.1)

Date of mailing
 (day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
 see form PCT/ISA/220

FOR FURTHER ACTION
 See paragraph 2 below

International application No.
 PCT/EP2004/010654

International filing date (day/month/year)
 21.09.2004

Priority date (day/month/year)
 23.09.2003

International Patent Classification (IPC) or both national classification and IPC
 A61M15/00, A61M15/08

Applicant
 GLAXO GROUP LIMITED

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1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the International application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/010654

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/010654

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	15-49
	No: Claims	1-14
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-49
Industrial applicability (IA)	Yes: Claims	1-49
	No: Claims	-

2. Citations and explanations

see separate sheet

Re Item V.

- 1 The following documents are referred to in this communication:
D1 : WO-A-03/020350 (OPTINOSE AS; DJUPESLAND PER GISLE (NO)) 13 March 2003 (2003-03-13)
D2 : WO-A-99/38555 (GOLDSTEIN; LEWIN TECH GMBH; GOLDEMANN RAUL (DE); SCHWARZWALD DETLEF) 5 August 1999 (1999-08-05)
D3 : US-A1-2002/117513 (HEMLINGER MICHAEL) 29 August 2002 (2002-08-29)
D4 : EP-A-1129786 (BECTON DICKINSON CO) 5 September 2001 (2001-09-05)
D5 : WO-A-01/36018 (RASOR JULIA S; RASOR NED S (US); CAPNIA INC (US)) 25 May 2001 (2001-05-25)
- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parenthesis applying to this document):
 - a medicament dispenser device comprising:
 - a housing including a dispensing outlet:
 - a medicament discharge device moveably housed within the housing, the medicament discharge device comprising a medicament container for storing the medicament to be dispensed and a medicament dispensing mechanism for dispensing medicament from the container to the outlet;
 - a user operable actuator moveable with respect to the medicament discharge device to apply an actuating force to the dispensing mechanism;
 - and
 - an actuation indicator responsive to application of said actuating force, wherein a pre-load means is provided to said user operable actuator to prevent application of the actuating force to the dispensing mechanism and actuation indicator until a pre-determined threshold force is applied to the user operable actuator.

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

The same objection also holds true in view of documents D2 (see page 11, lines 19 to 25), D3 (see figure 2) and D4 (see paragraph 28).

- 3 Independent claims 47 and 48 differ from the subject-matter of claim 1 in that the medicament discharge device can be replaced. Document D1 discloses these features (see figure 1). These claims are therefore not new (Article 33(2) PCT). Independent claim 49 differs from the subject-matter of claim 1 in that the medicament dispensing device additionally comprises an airflow generator. The aerosol canister of D1 corresponds with this feature. Claim 49 is therefore also not new (Article 33(2) PCT).
- 4 Dependent claims 2-14, 19-35 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). The reasons therefore are the following:

Claims 2 and 3:

These claims relate to where the medicament is applied. Documents D1 and D2 show the features of a mouthpiece and a nosepiece. These claims are therefore not new (Article 33(2) PCT).

Claims 4-8:

These claims relate to the type of dispensing mechanism of the medicament dispensing device. These different types are known, and disclosed in the documents of the search report.

Claim 9:

Actuation of a medicament dispenser device wherein the user operable actuator moves transversely to the medicament container is disclosed in documents D1 (see figure 8) and D4 (see figure 8). The position of the actuation device indicates that the actuation movement does not cross the longitudinal axis of the medicament container. This claim is therefore not new (Article 33(2) PCT).

Claims 10-14:

These claims relate to the actuator. Document D1 discloses a lever actuating the medicament dispenser through contact with the collar of the medicament container. This is consistent with the features of these claims. Claims 10-14 are therefore not new (Article 33(2) PCT).

Claims 15-18:

These claims relate to the actuation sensor and its potential use as a dose counter. There is always a need for information about remaining doses of medicament, as can be seen from document D2 (see page 8, lines 24 to 33). The features as disclosed in claims 15-18 do not appear to relate to a specific embodiment of a dose counter. These claims are therefore not considered to involve an inventive step (Article 33(3) PCT).

Claims 19-28 and 29-35:

These claims relate to the shape and location of the pre-load means. Documents D1, D2 and D4 all disclose a sliding surface obstructing the actuation of the medicament delivery device. The disclosure of claims 19-28 appears merely to be a variation on the position and shape of the profile used. These claims are therefore not considered to involve an inventive step (Article 33(3) PCT).

Claims 36-46:

Claim 36 refers to "the finger operable means", as if these means were already part of the claimed subject-matter. However, none of the claims 1-35 indicates that the device is to be actuated by fingers of the user.

The actuator medicament dispensing device as disclosed by D5 is considered to correspond to the features of these claims (finger operated, position of the end of the lever). These claims are therefore not considered to involve an inventive step (Article 33(3) PCT).